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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,626	09/29/2003	Michel Cormier	33392-712.201	4707
66956 7590 05/11/2007 WILSON SONSINI GOODRICH & ROSATI & MACROFLUX CORP. 650 PAGE MILL ROAD PALO ALTO, CA 94304			EXAMINER GHALI, ISIS A D	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 05/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/674,626	Applicant(s) CORMIER ET AL.	
	Examiner Isis A. Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 21-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 9 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/9/04; 4/11/05; 3/1/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed 08/09/2004, IDS filed 04/11/2005, IDS filed 03/01/2007, and election filed 02/28/2007.

Claims 1-39 are pending.

Species election as listed in sections 8, 9 and 10 in the previous office action have been withdrawn.

Response to Election/Restrictions

1. Applicant's election with traverse of Group II, device (a), claims 1-20 in the reply filed on 02/28/2007 is acknowledged. The traversal is on the ground(s) that the inventions I-IV are not distinct, and no serious burden on the examiner searching all the groups. This is not found persuasive because the product claims are distinct from the method claims because the product as claimed can be made by materially different process such molding. In addition, the two products are distinct because the product of invention I does not require dry coating while the invention II requires dry coating, and the two methods are distinct because invention III does not require the steps of itching and bending that are required by invention IV. Regarding the burden on the patent examiner, it is argued that the search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, however extensive since the patent examiner searches

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the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present four distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-8, 21-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/28/2007.

Claims 9-20 are included in the prosecution.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 11/259,010. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the conflicting claims of the copending application are directed to device for transdermal delivery of active agent comprising microprojections coated with the active agent and vasoconstrictor, recited by claim 17 of the copending application. The present claims and the copending claims are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 11/201,617. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the conflicting claims of the copending application are directed to device for transdermal delivery of active agent comprising microprojections coated with the active agent and

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vasoconstrictor, recited by claim 16 of the copending application. The present claims and the copending claims are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-81 of copending Application No. 11/084,636. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the conflicting claims of the copending application are directed to device for transdermal delivery of active agent comprising microprojections coated with the active agent and vasoconstrictor, recited by claims 21, 22, 68 and 69 of the copending application. The present claims and the copending claims are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 12, the expressions "salts" and

analogous" do not set out the metes and bounds of the claim. Recourse to the specification does not define the expressions.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/074173 ('173) in view of US 6,432,986 ('986).

WO '173 teaches apparatus for transdermal application of bioactive agent to the skin. The apparatus comprises plurality of microprojections coated with dry coating

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comprising active agents (abstract; paragraphs: 0007, 00039). The active agents is present in the coating in an amount less than 1 mg and include vaccine, LHRH, PTH, vasopressin, ACTH (1-24), interferon, EPO, FSH, GM-CSF, G-CSF, IL10 (paragraph 00014). The microprojections have length of less than 500 μm , thickness of 5-50 microns (paragraph 0037). The thickness of the coating on the microprojections is less than 25 μm , and preferably less than 10 μm (paragraph 00013). The coating may further comprise an adjuvant (paragraph 00057).

The difference between WO '173 and the present invention is that the WO '173 does not teach vasoconstrictors delivered from the coating with the active agent as claimed by claims 9 and 20, or its amount as claimed by claim 13.

US 986 teaches transdermal drug delivery wherein vasoconstrictor such as epinephrine in amount of 5 microgram per milliliter is added to drug in order to reduces the rate of drug absorption and prolongs the duration of its effect (col.6, lines 37-47).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide apparatus for transdermal application of bioactive agent to the skin comprises plurality of microprojections coated with dry coating comprising active agents and adjuvant as disclosed by WO '173, and replace the adjuvant with vasoconstrictor agent as disclosed by US '986, motivated by the teaching of US '986 that vasoconstrictor when added to transdermally delivered drug, it reduces the rate of drug absorption and prolongs the duration of its effect, with reasonable expectation of having apparatus for transdermal application of bioactive agent to the skin comprises plurality of microprojections coated with dry coating comprising active

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agents and vasoconstrictor that reduces the rate of drug absorption and prolongs the duration of its effect successfully.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

Isis Ghali

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